沈阳尚贤医疗系统有限公司
SHANGXIAN MINIMAL INVASIVE INC.

Date: 15th.SEP.2023.

Authorization

We, the undersigned Shangxian Minimal Invasive Inc.with address 1st Floor, Block B2-2, China medicine innovation park, Mulan road, Hi-tech development zone Benxi, 117004 Liaoning, China, herby we appoint "AG Medical" S.R.L., 17/6, N.Testimiteanu street, MD-2025, Chișinau, Republic of Moldova, to be authorized distributor/representative for registration, renewal, amendments of registration, at the responsible authorities of the Republic of Moldova.

For and on behalf of
沈阳尚贤医疗系统有限公司
SHANGXIAN MINIMAL INVASIVE INC.
Shangxian Minimal Invasive Inc.

Digitally signed by Rusu Cristina
Date: 2023.09.16 17:48:47 EEST
Reason: MoldSign Signature
Location: Moldova

Authorized signature(s)

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 2114740-1

Manufacturer: Shangxian Minimal Invasive Inc.
1st Floor, Block B2-2, China medicine innovation park, Mulan road,
Hi-tech development zone, Benxi, 117004 Liaoning,
P.R. China

Products: Disposable Biopsy Forceps, Disposable Endoscopic Distal Attachments, Disposable Hemostasis Clips and Delivery Systems, Capsule Endoscopy Systems, Disposable Hemostasis Clips, Disposable Grasping Forceps, Disposable Injection Needles and Disposable Polypectomy Snares

Aspects of Manufacture concerned Securing and Maintaining Sterile Conditions of Disposable Guide Wires

Replaces Approval, Registration No.: HD 60148689 0001

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 190130980 170

Effective date: 2021-05-24

Expiry date: 2024-05-26

Issue date: 2021-05-24

Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 2114740-1

Manufacturer: Shangxian Minimal Invasive Inc.
1st Floor, Block B2-2, China medicine innovation park, Mulan road,
Hi-tech development zone, Benxi, 117004 Liaoning,
P.R. China

The scope of certification includes the following sites:

No.	Location	Product groups
/01	Shangxian Minimal Invasive Inc. 1001, IT Int'l Building, No.3 West Yuanhang Road, Hunnan New District, Shenyang, 110179 Liaoning, P.R. China	Same as the above mentioned products
/02	Shangxian Minimal Invasive Inc. No.1, Floor 1, Building 1, West Binhe Road, Benxi Economic Development Zone, Liaoning, P.R. China	Same as the above mentioned products

Report No.: 190130980 170

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TÜV Rheinland LGA Products GmbH

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EC DECLARATIONOF CONFORMITY

According toMDD 93/42/EEC, amended by 2007/47/EC

Manufacturer:	Shangxian Minimal Invasive Inc. 1st Floor, Block B2-2, China medicine innovation park, Mulan road, Hi-tech development zone, 117004 Benxi, Liaoning, China
EuropeanRepresentative:	MedPath GmbH Mies-van-der-Rohe-Strasse8 80807 Munich, Germany
Product name:	**Disposable Grasping Forceps**
Product code / Catalogue number:	UMDNS-CODE/Preferred Terms: 11775 Model: MI-FG-TY(ZJ/3ZX/4ZX/5ZX)-18(23)*800(1200/1600/1800/2300/2500); MI-FG-CXDZ-18(23)*800(1200/1600/2300/2500).
Classification acc. to MDD Ax. IX:	Class IIa, rule 7
Applied Standards:	EN 62366-1:2015+AC:2015, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-7:2008, ISO 10993-10:2010, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018, EN ISO 11737-2:2020, ISO 11135:2014, MEDDEV. 2.7.1 Rev.4, MEDDEV 2.12/2, ASTM D4169-2016
Conformity assessment procedure:	MDD Annex II (without II.4)
CE certificate No.:	HD 2114740-1
Name and ID of the Notified Body:	TÜV Rheinland LGA Products GmbH CE0197

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Directive 93/42/EEC on Medical Devices (MDD), amended by 2007/47/EC. All supporting documentations are retained under the premises of the manufacturer.

For and on behalf of

沈阳尚贤医疗系统有限公司

SHANGXIAN MINIMAL INVASIVE INC.

Shenyang, Jan. 22th 2022

Signature: Li Yuxia

General Manager

Authorized signature(s)

Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

DECLRAȚIE
PE PROPRIE RASPUNDERE

Solicitantul ***"AG Medical" S.R.L.****, cu sediul în* ***mun. Chișinău, str. N.Testemitanu 17/6****, tel:* ***068864448****, e-mail:* sc.agmedical.srl@gmail.com,

declar pe proprie răspundere, cunoscând prevederile art. 352^1 *, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:*

PRODUCT:
DISPOSABLE GRASPING FORCEPS

MODEL:

1. *MI-FG-ZJ-23*2300- 40*

Sunt autentice și corespund realității

Cristina Rusu, administrator *Semnătura* _____

16.09.2023

Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 1 din 16.09.2023

Solicitantul "AG Medical" S.R.L., cu sediul în mun. Chișinău, str. N.Testemitanu 17/6, tel: 068864448, e-mail: sc.agmedical.srl@gmail.com, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Product: *DISPOSABLE GRASPING FORCEPS*
Model: MI-FG-ZJ-23*2300- 40

Se anexează următoarele acte:

1. Declarație de Conformitate CE
2. Certificatul de Conformitate CE
3. Actul prin care producătorul își desemnează reprezentantul
4. Declarație pe propria răspundere.

Cristina Rusu
16.09.2023

Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	